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10/559,533	12/02/2005	**Tadashi Okiyama**	061639-0318680	9144

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EXAMINER	
PATEL, SHEFALI DILIP	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/559,533	OKIYAMA, TADASHI	
	Examiner	Art Unit	
	SHEFALI D. PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-11,15-19,21,22 and 25-27* is/are pending in the application.

4a) Of the above claim(s) *8-11 and 17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,15,16,21,22 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on October 29, 2010, has been entered.

Acknowledgments

2. In the reply, filed on October 29, 2010, Applicant amended claims 1, 2, 15, 17, and 21.

3. Applicant cancelled claims 12-14, 23, and 24 are cancelled.

4. In the final rejection of May 7, 2010, Examiner rejected claims 1, 15, and 21 under 35 USC 112, 1st paragraph, for failing to comply with the written description requirement by containing new matter of "at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate". After the pre-appeal conference, Examiner changed the 35 USC 112, 1st paragraph, rejection from a new matter issue to an enablement issue, as the claims are directed to a non-elected embodiment of Figure 14 and the claim limitation is not discussed with respect to the elected embodiment of Figures 2-5. In the reply, Applicant submits that the elected embodiment of Figures 2-5 teaches the flow of fluid up to regions 1141 and 1142. However, in relation to

Figures 2-5, it is not described that fluid flow in regions 1141 and 1142 is contacted with the back surface of the septum. In Figure 4, it appears that fluid contacts the slit surface of the septum, not the back surface of the septum, as the back surface of the septum is not exposed. Paragraphs [0043][0044], as cited by Applicant, of the Specification do not positively recite that is it specifically the back surface of the septum that is contacted by the first fluid. Rejection is maintained.

5. Examiner rejected claims 1, 15, and 21, under 35 USC 112, 2nd paragraph, as the new limitation that of "at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate" is indefinite as it is unclear what element the back surface is exposed to. In the reply, Applicant argues that the claims themselves specifically recite that the first circulating fluid is the element that is exposed to a portion of the back surface of the septum. However, even though the claim recites that the first fluid contacts the back surface of the septum, the first fluid is not what makes the back surface exposed. It is unclear what the back surface of the septum is exposed in relation to (i.e. to the outside environment, to the interior of the port, etc.). Rejection is maintained.

6. Currently, claims 1-5, 7, 15, 16, 21, 22, and 25-27 are under examination.

Claim Objections

7. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

In regards to claim 2, the limitation that "the body portion… is provided with an inner cavity" does not further limit the subject matter of claim 1, as claim 1 already recites that the body portion is provided with an inner cavity.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 15, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In regards to claims 1, 15, and 21, the limitation that "at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate" has an enablement issue as the limitation is not discussed with respect to the elected embodiment of Figures 2-5 and appears to be directed to the non-elected embodiment of Figure 14. In relation to Figures 2-5, it is not described that fluid flow in regions 1141 and 1142 is contacted with the back surface of the septum. In Figure 4, it appears that fluid contacts the slit surface of the septum, not the back surface of the septum, as the back surface of the septum is not exposed.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 15, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claims 1, 15, and 21, the limitation that "at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate" is indefinite as it is unclear what element the back surface is exposed to (i.e. to the outside environment, to the interior of the port, etc.).

In regards to claims 15 and 21, the claims recite the limitation "the annular protrusion". There is insufficient antecedent basis for this limitation in the claims, as "an annular protrusion" has not been previously introduced in each one of independent claims 15 and 21.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1, 2, 4, 7, 15, 21, 22, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jepson et al (US 6,193,697), and further in view of Vedder (US 5,441,487).

In regards to claim 1, Jepson et al teaches a mixture injection port (Figures 3, 4A, and 4B) comprising:

a. a channel tube unit (pre-slit injection site [34]) including a body portion (housing [40]) that is provided with an inner cavity and a leg portion (fluid flow member [46]) that is provided with a narrow tube portion having a smaller width than that of the inner cavity

b. a septum (septum [52]) covering one end of the channel tube unit and having a slit (opening [66]) into which a tube member is inserted

Jepson et al does not teach a circulating member provided in the channel tube unit below the septum, the circulating member being separate from the channel tube unit. Vedder teaches a mixture injection port (Figures 1-4) with a circulating member (disc valve [14]) that is separate from a channel tube unit (medical site [10]). The circulating member [14] comprises a plate portion (disc [28]) arranged to change direction of flow of a first fluid injected from the inserted tube member or a second fluid flowing from the other end of the channel tube unit and an edge portion (actuator [26]) that protrudes upwardly towards the septum from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port, of Jepson et al, with a circulating member, as taught by Vedder, as the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44).

In regards to claim 2, in a modified port of Jepson et al and Vedder, Jepson et al teaches that the body portion [40] includes an opening that is covered by the septum [52] and that is

provided with an inner cavity for accommodating the septum that is deformed by the insertion of the tube member and wherein the narrow tube portion [46] is configured to provide communication between the inner cavity and the other end of the channel tube (Figure 3).

In regards to claim 4, in a modified port of Jepson et al and Vedder, Jepson does not teach a plate portion. Vedder teaches that the plate portion [28] of the circulating member is provided with a holding portion (nipple [32]) on its back face that is engaged with the narrow tube portion and holds the circulating member inside the channel tube (Figure 1). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of the modified port of Jepson et al and Vedder, with a holding portion, as taught by Vedder, as the holding portion will provide a seat for the plate portion in engagement of the portion of the port containing the narrow tube portion (column 3, lines 43-46).

In regards to claim 7, in a modified port of Jepson et al and Vedder, Jepson does not teach a circulating member. Vedder teaches a groove (opening through interior [36]) for guiding the first fluid or the second fluid that is formed on an inner circumferential surface and an outer circumferential surface of the edge portion [26]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the edge portion, of the modified port of Jepson et al and Vedder, with a groove, as taught by Vedder, as the groove of the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44).

In regards to claim 15, Jepson et al teaches a mixture injection port (Figures 3, 4A, and 4B) comprising:

a. a channel tube unit (pre-slit injection site [34]) including a body portion (housing [40]) that is provided with an inner cavity and a leg portion (fluid flow member [46]) that is provided with a narrow tube portion having a smaller width than that of the inner cavity

b. a septum (septum [52]) covering one end of the channel tube unit and having a slit (opening [66]) into which a tube member is inserted

Jepson et al does not teach a circulating member provided in the channel tube unit below the septum, the circulating member being separate from the channel tube unit. Vedder teaches a mixture injection port (Figures 1-4) with a circulating member (disc valve [14]) that is separate from a channel tube unit (medical site [10]). The circulating member [14] comprises a plate portion (disc [28]) arranged to change direction of flow of a first fluid injected from the inserted tube member or a second fluid flowing from the other end of the channel tube unit and an edge portion (actuator [26]) that protrudes upwardly towards the septum from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port, of Jepson et al, with a circulating member, as taught by Vedder, as the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44).

In regards to claims 21 and 22, Jepson et al teaches a method for transferring a fluid to or from a body through a mixture injection port (Figures 3, 4A, and 4B), the mixture injection port comprising a channel tube unit [34] including a body portion [40] that is provided with an inner cavity and a leg portion [46] that is provided with a narrow tube portion having a smaller width than that of the inner cavity and a septum [52] covering

one end of the channel tube unit and having a slit [66], the method comprising:

a. inserting a tube member (piercing member [98]) into the slit (Figures 4A-4B)

b. injecting a first fluid into the tube member or a second fluid into an other end of the channel tube unit (column 8, lines 46-59)

c. circulating the first fluid or the second fluid towards the septum side (column 8, lines 46-59)

d. guiding the first fluid to the other end of the channel tube unit below the septum or the second fluid to a top portion of the tube member (column 8, lines 46-59)

Jepson et al does not teach a circulating member provided in the channel tube unit below the septum, the circulating member being separate from the channel tube unit. Vedder teaches a mixture injection port (Figures 1-4) with a circulating member (disc valve [14]) that is separate from a channel tube unit (medical site [10]). The circulating member [14] comprises a plate portion (disc [28]) arranged to change direction of flow of a first fluid injected from the inserted tube member or a second fluid flowing from the other end of the channel tube unit and an edge portion (actuator [26]) that protrudes upwardly towards the septum from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the

port/method, of Jepson et al, with a circulating member, as taught by Vedder, as the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44).

In regards to claims 25-27, in modified port/method of Jepson et al and Vedder, Jepson et al teaches that at least a portion of the exposed back surface of the septum [52] becomes exposed when the septum is deformed by the insertion of the tube member (Figures 3 and 4B).

14. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jepson et al and Vedder, as applied to claims 2 and 15 above, and further in view of Cote (US 5,775,671).

In regards to claim 3, in a modified port of Jepson et al and Vedder, Jepson et al does not teach a plate portion. Vedder does not teach a groove that is formed on a surface on the inner cavity side of the plate portion of the circulating member, the groove extending in a direction different from a direction from which the first fluid is injected from the inserted tube member, and wherein the first fluid is allowed to flow along the groove so that the direction of flow of the first fluid is changed. Cote teaches a mixture injection port (Figures 1, 2A, 3, and 4) with a groove (spaces in between raised areas [58]) that is formed on a surface on the inner cavity side of a plate portion (transverse wall [60]) of a circulating member (actuator [50]), the groove extending in a direction different from a direction from which the first fluid is injected from an inserted tube member. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of the modified port of Jepson et al

and Vedder, with a groove, as taught by Cote, as the groove of the plate portion will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the plate portion (Abstract)(column 1, lines 36-38)(column 5, lines 1- 9)(column 5, lines 23-40).

In regards to claim 16, in a modified port of Jepson et al and Vedder, Jepson et al does not teach a circulating member. Vedder teaches a groove (opening through interior [36]) that is formed on a surface of the edge portion [26] of the circulating member and the first fluid flows along the groove towards the septum side. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the edge portion, of the modified port of Jepson et al and Vedder, with a groove, as taught by Vedder, as the groove of the circulating member will act as a means for regulating flow through the port by opening to complete a fluid connection through the port in both first and second fluid flow directions and by closing to prevent fluid flow (column 5, lines 26-44). However, Vedder does not teach another groove that is formed on a surface of the plate portion [28] of the circulating member and the first fluid flows along the another groove towards the edge portion. Cote teaches a mixture injection port (Figures 1, 2A, 3, and 4) with a groove (spaces in between raised areas [58]) that is formed on a surface of a plate portion (transverse wall [60]) of a circulating member (actuator [50]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of the modified port of Jepson et al and Vedder, with another groove, as taught by Cote, as the another groove of the plate portion will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass

through both the interior and exterior flow paths of the plate portion (Abstract)(column 1, lines 36-38)(column 5, lines 1- 9)(column 5, lines 23-40).

15. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jepson et al and Vedder, as applied to claim 4 above, and further in view of Arnett (US 5,817,069).

In regards to claim 5, in a modified port of Jepson et al and Vedder, Jepson et al does not teach a plate portion. Vedder teaches a plate portion and a holding portion; however, Vedder does not teach a groove for guiding the first fluid or the second fluid that is formed in the back face of the plate portion and the holding portion. Arnett teaches a mixture injection port (Figure 1, assembly [10]) comprising a groove (second fluid passageway [106]: openings [108][110]) of guiding a first fluid or a second fluid that is formed in the back face of a plate portion (actuator [20]) and a holding portion (second actuator end [98] and exterior surface [100]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion and the holding portion, of the modified port of Jepson et al and Vedder, with a groove, as taught by Arnett, as the groove of the plate portion and holding portion will allow fluid to freely flow through the groove from the inlet of the port to the outlet of the port in either direction (column 5, lines 25-32).

Response to Amendment

16. The amendment to the claims filed on October 29, 2010, does not comply with the requirements of 37 CFR 1.121(c) because the incorrect status identifier of (Cancelled - Previously Presented) has been given to claim 2. Claim 2 has been amended and is not stated as

cancelled in the Remarks. Claim 2 should have the status identifier (Currently amended).

Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) Claims. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) Claim listing. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) When claim text in clean version is required. The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.

(4) When claim text shall not be presented; canceling a claim.

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) Reinstatement of previously canceled claim. A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Since the reply filed on October 29, 2010, appears to be bona fide, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance with 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Response to Arguments

17. Applicant's arguments with respect to claims 1-5, 7, 15, 16, 21, 22, and 25-27 have been considered but are moot in view of the new ground(s) of rejection, based on the insertion of subject matter not previously presented in the claims into independent claims 1, 15, and 21.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Brimhall et al (US 5,242,393).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
2/9/2011
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767